K071093

5. SUMMARY OF SAFETY AND EFFECTIVENESS

(According to 21 CFR 807.92)

DEC 0 6 2007

DATE OF SUBMISSION:	April 12, 2007
SUBMITTER:	President, Chin Lin Huang SAN SHIH Electrical Enterprise Co., Ltd. No. 209, Sec. 3, County Boulevard, Pan Chiao City, 22050, Taiwan Hsien, ROC TEL: 886-2-2253-5336 FAX: 886-2-2253-0442
ESTABLISHMENT OWNER NO:	9096360
OFFICIAL CONTACT:	Dr. JEN, KE-MIN ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY No. 58, Fu-Chiun Street. Hsin Chu City, 30067, Taiwan, ROC TEL: 886-3-5208829 FAX: 886-3-5209783 E-mail: ceirs.jen@msa.hinet.net
TRADE NAME:	SAN SHIH Powered Muscle Stimulator, 202
COMMON/USUAL NAME:	Electrical Muscle Stimulator
CLASSIFICATION NAME:	Powered Muscle Stimulator
REGULATION NUMBER:	890.5850
PREDICATED DEVICE:	HOME CARE Powered Muscle Stimulator, K023000
INTENDED USE:	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion

Description of Device:	A sequenced system for transcutaneous muscle stimulation consists of a stimulator, a sequencer for channel selection, patient cable, and electrodes applied to the skin. Various types of waveforms may be output to generate the desired effect on the muscle(s) to be treated, and the patient is given control of the signal intensity for personal safety and comfort. Sequenced system may have more than on output channel in order to operate bilaterally on the body or to treat multiple regions simultaneously or serially in a prescribed sequence.
Non-Clinical Tests Submitted:	The 202 has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for safety of nerve and muscle stimulators. Accessories also meet safety requirements: 510(k) electrodes are specified, and the patient cable utilizes shrouded connectors to meet lead wire safety requirements. System level testing including waveform testing was performed in combination the 202 stimulator.
Clinical Tests Submitted:	None
Conclusion:	As the product description and tests as above, the new device: **SAN SHIH Powered Muscle Stimulator 202** is as safe and effective as, and the function in a manner equivalent to the predicate device: **HOME CARE Powered Muscle Stimulator, K023000**. Thus the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2007

SAN SHIH Electrical Enterprise Co., Ltd
% ROC Chinese-European Industrial Research Society
Dr. Jen, Ke-Min
No. 58, Fu-Chiun Street
Hsin Chu City, 30067, Taiwan, ROC

Re: K071093
Trade/Device Name: SAN SHIH Powered Muscle Stimulator, 202
Regulation Number: 21 CFR 890.5850
Regulation Names: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: October 31, 2007
Received: November 20, 2007

Dear Dr. Jen, Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K

Device Name: SAN SHIH Electrical Enterprise Co., Ltd.
SAN SHIH Powered Muscle Stimulator, 202

Indications for Use :

- *Specific indications:* used to apply an electrical current to electrodes on patient's skin to function as:
  - Relaxation of muscle spasms
  - Prevention or retardation of disuse atrophy
  - Muscle re-education
  - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
  - Maintaining or increasing range of motion

- *Clinical settings*: The device should only be used under medical supervisions for adjunctive therapy for the treatment of medical diseases and conditions.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071093